

## EXHIBIT IV

REEXAMINATION  
REASONS FOR PATENTABILITY / CONFIRMATION

Reexamination Control No. 90/007,252

Attachment to Paper No. \_\_\_\_\_

Art Unit 3993.

See attached sheet.

Bibhu Mohanty  
(Examiner's Signature)

BIBHU MOHANTY  
PRIMARY EXAMINER

### STATEMENT OF REASONS FOR PATENTABILITY AND/OR CONFIRMATION

1. The following is an examiner's statement of reasons for patentability and/or confirmation of the claims found patentable in this reexamination proceeding:

A. Claim 1, with the other elements of the claim, requires a bioresorbable implant for human administration consisting essentially of microspheres or microparticles suspended in a gel consisting essentially of non-animal origin. The claim further requires the microspheres or microparticles to consist of at least one polymer of non-animal origin selected from a group consisting of specific polymers (lactic acid and glycolic acid polymers, and lactic acid-glycolic acid co-polymers).

None of the prior art references disclose the specific limitations of claim 1, or suggest the limitations of claim 1 when taken in combination with the other references of record.

Note initially that a "gelatin" is conventionally defined as being made from animal products. Webster's New World Dictionary, Third Edition, states that a gelatin is a "mixture of proteins extracted by boiling skin, bones, horns, etc." Further, a "gel" is separately defined as a "jellylike substance formed by cooling a colloidal solution into a solid" (see Webster's New World Dictionary, Third Edition).

The specification of the Patent in this reexamination proceeding, US Patent 6,716,251, states in column 3, lines 34-35, "The implant does not require a test of

allergenicity. It does not contain any product of animal origin". The use of products of animal origin may cause allergic reactions.

US Patent 5,344,452 to Lemperle discloses using an implant with a histocompatible solid in a gel. However, Lemperle does not show the use of the histocompatible solid to be one of the specific polymers as required by claim 1 (that is lactic acid and glycolic acid polymers or lactic acid-glycolic acid co-polymers). Further, Lemperle does not disclose the gel or acid polymers to be made from "non-animal origin". There is no motivation in the references of record to modify the Lemperle reference to use the specific claimed acid polymers and to use acid polymers and a gel of non-animal origin.

EP Patent Application EP 0269921 to Muranishi does disclose using polylactic acid microspheres but does not disclose using a gel as claimed in claim 1. Further, Muranishi does not disclose a gel or acid polymers of non-animal origin. There is no motivation in the references of record to modify the Muranishi reference to use a gel or acid polymers of non-animal origin.

EP Patent Specification EP 0330180 B2 to Hyon does disclose using a polylactic acid polymer in gelatin. However, the polylactic acid polymer and gelatin are not disclosed to be of non-animal origin. Further, note that the gelatin used in the Hyon reference as disclosed is not a gel. There is no motivation in the references of record to modify the Hyon reference to use a gel or acid polymers of non-animal origin.

US Patent 3,773,919 (Boswell) shows a polylactide as claimed, but does not disclose using a gel. Further, Boswell does not disclose a gel or acid polymers using